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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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12/15/00

EXAMINER

MANSCHER, A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED:

16
12/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/097,791

Applicant(s)

Boyce-Jacino et al.

Examiner

Ardin Mars hel

Group Art Unit

1631



☒ Responsive to communication(s) filed on Sep 25, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-30 is/are pending in the applicat

Of the above, claim(s) 29 and 30 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-30 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). (3 sheets)

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ CRF Problem Report

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' arguments, filed 9/25/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are reiterated. They constitute the complete set presently being applied to the instant application.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because no submission of computer readable form sequences has been submitted. See the CRF Problem Report which is enclosed herewith indicating a lack of submission of sequences on the filed diskette. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action.

Claim 2 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite as to whether the primer therein cited is limited to 3-7 bases or is limited by being at least 3-7 bases but including longer primer practice because of the open claim language term "comprises" in line 1. In other

words, it is unclear whether the "comprises" word limits the primer length or the 3-7 bases limitation. This rejection is reiterated from the previous office action, mailed 3/21/00, because the open claim language is still deemed to unclearly define what the primer may contain beyond the polynucleotide of 3-7 bases. Clarification via clearer claim wording is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-27 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Cantor et al. (P/N 5,795,714).

This rejection is reiterated and maintained from the previous office action, mailed 3/21/00. Applicants firstly argue that the disclosure of Cantor et al. at column 4, line 10, through column 5, line 53, describes a specific type of probe as well as a specific method, neither of which are encompassed by the instant claims. This is an allegation without describing or pointing to specifically what differences exist between the Cantor et al. disclosure and the instant claims and therefore

non-persuasive. This is additionally non-persuasive because this column 4-5 citation in Cantor et al. was not pointed to in the previous office action in support of this rejection. Therefore, applicants' arguments are not directed to any part of the basis for this rejection. Applicants then point to column 7, lines 32-36, of Cantor et al. regarding thermodynamic effects. It is not seen how such effects which may enhance certain binding reaction situations has any relationship to whether a reaction occurs or not, albeit sometimes more readily versus less readily under other conditions. Applicants then admit at the top of page 7 of their REMARKS that Cantor et al. does disclose enzymatic extension as part of the therein disclosed method. This admission contains the phrase "a few references" which apparently is meant to negate their importance. In response it is noted that only one disclosure of an invention is sufficient for a prior art reference to support a rejection of that invention. Applicants then argue that the enzymatic extension has limited use including sequencing. In response such extension clearly includes hybridization during the extension reaction contrary to the allegation of applicants thus supporting this rejection. Applicants then argue that the two paragraphs in column 17, line 32, through column 18, line 4, lack a scanning step of the instant claims. In response the process of forming an extension product requires hybridization between a primer moiety and a

target as well as a polymerase binding followed by extension. These binding reactions occur via the diffusion of the component molecules in solution followed by binding when the appropriate site is found. This is clearly a scanning process which is still deemed to support the rejection. Applicants then argue that the extension product is not detected but confusingly admit as noted above that sequencing extension products are produced. Such a sequencing reaction must inherently be detected via the extension product in order to determine the sequence. Applicants then argue that the Sanger dideoxy sequencing only reveals the sequence adjacent to the probe. In response this is non-persuasive because hybridization of the primer or probe region is firstly required before the extension product may be made by the polymerase enzymatic action. The very hybridization of this primer region is a recognition and determination of the presence of the region in the target which is complementary to said primer/probe region and thus determines this region also as is also required in the instant claims. Applicants then argue that only the probe length is cited for rejection of instant claim 2 and not the primer. In response the probe described in the reference is utilized as a primer also and therefore anticipates instant claim 2 contrary to the argument of applicants. Applicants then argue that claims 3, 4, 13-15, and 17 are not anticipated by referring to the arguments regarding instant claim

1 versus the reference. These arguments have already been responded to above as non-persuasive and are equally non-persuasive regarding these dependent claims. Applicants then argue that their spacer region may be comprised of "other moieties" than nucleotides as utilized in the reference. This is non-persuasive in that the instant claims are not limited to such "other moieties" and thus include the Cantor et al. spacer embodiments thus continuing to support this rejection. Applicants then argue that the capture, spacer, and primer regions of claim 4 are distinct units. In response these units are characterization of segments of a hybridizable segment as utilized in Cantor et al. without any distinction in instant claim 4 as to what distinguishes these moieties from a hybridizable segment as utilized in Cantor et al. which may arbitrarily be called capture, spacer, or primer region of a somewhat lengthy nucleotide sequence. The lack of any distinction thus supports the maintaining of this rejection as the primer/probes of Cantor et al. serve the functions of claim 4 and may be divided up into segments and named what is given in claim 4 thus anticipating claim 4. Similarly, instant claims 13 and 14 are argued by applicants in that certain moieties are separate reagents. It is not seen in claims 13 or 14 that there is therein any limitation directed to a separation of reagents. That is, the moieties of these claims may be covalently linked

together as in a probe or primer as segments therein and still anticipate these claims as does the disclosure of Cantor et al. Applicants then argue that instant claims 5-12, 16, and 18-27 are not anticipated due to arguments applied against other claims such as claims 1, 3, and 4. The arguments against these other claims have been responded to above as non-persuasive and are equally non-persuasive when reiterated regarding claims dependent therefrom. Applicants then argue that Cantor et al. does not disclose a spacer region regarding the instant claim 18 limitations but acknowledges a stabilizer region in Cantor et al. In response the naming of a region a stabilizer versus a spacer does not negate the presence of a chemical region which physically anticipates the claim practice. That is, it is non-persuasive regarding overcoming a rejection to utilize a different naming when the chemical region is present in the practice of the prior art reference as it is in the instant invention thus supporting the rejection. In summary, this rejection is maintained from the previous office action, mailed 3/21/00.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cantor et al. (P/N 5,795,714) in view of Pease et al. (Ref CB).

This rejection is maintained from the previous office action, mailed 3/21/00. Applicants argue that because Cantor et al. does not support the rejection then the combination of Cantor et al. and Pease et al. cannot support this rejection. The non-persuasiveness of the arguments regarding Cantor et al. has been summarized above and are equally non-persuasive here. Applicants then argue that column 8, lines 31-37, fails to suggest the high density array practice of Pease et al. In response Cantor et al. clearly suggests the practice of very large probe arrays which

indicates that the array size falls into the category of the large array microchip hybridization practice. Pease et al. is directed to such large arrays and utilizes and motivates high densities for the benefit of obtaining more and more information as the array density or size increases which clearly motivates both large array size as well as density.

One citation on the enclosed PTO Forms 1449 has been lined through to avoid duplication of citation because it was previously cited on a PTO Form 892.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 29 and 30 drawn to an invention non-elected with traverse in Paper No. 8, filed 1/13/00. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 13, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER